K113249

3. 510(k) Summary for Puritan UTM-RT Collection and Transport System (UTM-RT)

MAR - 1 2012

3.1. **Sponsor**

Puritan Medical Products LLC

31 School Street, PO Box 149

Guilford, ME 04443-0149 U.S.A.

3.2 **Device Name**

Classification name: Transport Culture Medium Device

Common Name: Microbiological Specimen Collection and Transport System

Proprietary Name: Puritan UTM-RT Collection and Transport System

3.3. **Regulatory Information**

A. Regulatory Section: 21 CFR 866.2390

B. Classification: I

C. Product Code: JSM

D. Panel: Microbiology

3.4. **Device Description**

Puritan UTM-RT is an enclosed system recommended for the collection and transport of viruses, chlamydiae, mycoplasmas and ureaplasma. The osmotically balanced and buffered culture medium contains Hank's balanced salt solution with a pH indicator, sucrose as a preservative, protein and gelatin as stabilizers. Antimicrobial agents are incorporated to minimize commensal bacterial and fungus contamination.

Puritan UTM-RT is comprised of a conical polypropylene vial filled with three 3-mm glass beads and 1.5ml or 3 ml of the transport medium, affixed with a high density polyethylene cap. Each unit of Puritan UTM-RT is provided in a peel pouch containing one of the following swab combinations:

- 1ml UTM with ultrafine tip HydraFlock® Swab

- 3ml UTM with one elongated tip HydraFlock® and one ultrafine tip swab
- 3ml UTM with elongated tip HydraFlock®® swab
- 3ml UTM with mini-tip HydraFlock® swab, scored shaft
- 3ml UTM with ultrafine HydraFlock® tip swab
- 3ml UTM vial with 2 reg polyester tip swabs, scored shaft
- 3ml UTM vial with regular polyester tip and one wire/plastic shaft with polyester tip

3.5. **Intended Use**

Puritan UTM-RT Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing laboratory. The specimen transported in the **Puritan UTM-RT** can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture.

3.6. **Indication(s) for use**

Puritan UTM – RT Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing laboratory. The specimen transported in the Puritan UTM - RT can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture.

3.7. **Substantial Equivalence Determination**

A. Predicate Device.

- Copan (BD) UTM-RT
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B. Predicate Devise 510(k) Number(s)

- K 04 2970

C. Comparison of the test device with Predicate device

The Puritan UTM-RT Transport Systems are similar in design, manufacturing, packaging and intended use to the predicate devices. Both Puritan and predicate systems are single use devices intended for the collection and transport of viruses, chlamydiae, mycoplasmas and ureaplasmas.

Puritan Versus Competitor Similarities		
Item	Test Device	Predicate Device Copan (BD)
Intended Use	Collection and transport of clinical specimens containing virus, Chlamydia, mycoplasma or ureaplasma	Same
Single-use Devise	Yes	Yes
Medium Formulation	Hank's Balanced Salt Solution Bovine Serum Albumin L-cysteine Gelatin Sucrose L-glutamic acid Hepes buffer Vancomycin Amphotericin B Colistin Phenol red	Hank's Balanced Salt Solution Bovine Serum Albumin L-cysteine Gelatin Sucrose L-glutamic acid Hepes buffer Vancomycin Amphotericin B Colistin Phenol red
pH	7.3 ± 0.2	Same
Storage Temperature	2-25°C (refrigerated and room temperature)	Same
Volume	1.5 ml; 3 ml; or 10 ml;	Same
Glass Beads	3 x 3 mm	Same
Container	Plastic; conical bottom	Same
Product Configuration	Medium in tubes & Cap System including Medium and swab in peel pouch option.	Same Same
Swab Shaft	Plastic	Same

Puritan Versus Competitor Differences		
Item	**Device**	**Predicate**
Swab Tip	HydraFlock® Swab (Polyester)	Nylon Flock swab
Shelf Life	15 months	12 months

3.8. Standard/Guidance Document Referenced

Quality Control of Microbiological Transport Systems M40-A, Clinical Laboratory and Standards Institute (CLSI), Wayne, PA, 2003.

3.9. Performance testing – Bench

Microbial recovery studies were carried out to establish the performance of **Puritan UTM-RT** system.

Recovery:

The following virus strains were chosen for recovery study:

Adenovirus	Cytomegalovirus
Echovirus Type 30	Herpes Simplex Virus Type I
Herpes Simplex Virus Type II	Influenza A
Parainfluenza Type 3	Respiratory Syncytial Virus
Varicella Zoster Virus	

The following chlamydiae strains were chosen for recovery study:

Chlamydia pneumonia Strain CM-1
Chlamydia trachomatis Type 1 Strain UW-12/UR

The following mycoplasmas and ureaplasma were chosen for recovery study

Mycoplasma hominis
Mycoplasma pneumonia
Ureaplasma urealyticum

The survival and recovery of viruses, chlamydiae, mycoplasmas and ureaplasmas was tested to determine the performance characteristics of Puritan Universal Transport Medium UTM-RT. The test methodology comprised of preparing neat stocks of the above microorganisms for testing. Two different dilutions of neat stock suspensions were prepared and, from these, 100 µl were directly inoculated onto swabs in triplicate. The swabs were transferred into the transport medium and held at both 4° C and room temperature (20-25° C) for the required amount of time. At key time points following inoculation (0, 24, and 48 h), each sample was vortexed after which an aliquot of the suspension was inoculated into shell vials or suitable culture media. Viability of viruses and chlamydiae was determined by shell vial assay followed by immunostaining and enumeration of fluorescent foci. The viability of mycoplasmas and ureaplasmas was determined using direct culture methods onto appropriate growth media followed by enumeration of colony forming units (CFU). Cultures were processed by standard laboratory techniques and examined following optimal incubation periods. The results demonstrate the ability of Puritan Medical Products UTM-RT to sustain the viability and recovery of test bacteria and viruses for at least 48 hrs at 4° C and room temperature (20-25° C).

3.10. Stability and shelf life

a. Recovery stability

The following strains were chosen for shelf life stability testing:

Cytomegalovirus
Herpes Simplex Virus Type II
Respiratory Syncytial Virus
Chlamydia pneumonia
Mycoplasma pneumonia

Prior to stability testing, neat stocks of test organisms were prepared and assessed for viable concentration. Three lots of the test device beyond the expiration point and one newly prepared lot were challenged with one concentration of each neat stock. Device performance was assessed by spiking swabs that accompanied each transport system with the chosen test dilution. Swabs were then transferred into the UTM, stored at different temperatures (refrigerated and room temperature) and held at 0, 24 and 48 hours. Viability/stability of each test organism under the defined conditions was evaluated through cell culture and immunofluorescence staining (viruses and Chlamydia) or standard bacterial culture methods (Mycoplasma). Culture data between the test and predicate devices were statistically analyzed and compared.
For all four lots, test viruses and bacteria could be quantified through 48 hours at the two storage temperatures. In general, refrigerated storage resulted in higher test strain recoveries and increased stability. One- way analysis of variance demonstrated statistical differences ($p<0.05$) between the lots under certain storage conditions, primarily between refrigerated and room temperature storage; this was concluded to be insignificant from the clinical stand point. Storage stability testing indicated maintenance of the test device performance up to and including the expiration date.

b. pH stability
The pH of the test device was measured at predetermined time intervals up to 18 month after the manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan UTM-RT. All samples tested were found to maintain pH within the specified target range.

c. Antibiotics Stability Test
Antibiotics stability of test device was evaluated using 3 expired lots and a new lot of test device and compared to the predicate device. All products tested demonstrated the ability to control bacterial activities up to 72 hours.

3.11. Cytotoxicity
Cytotoxicity testing using an MRC-5 cell line in conjunction with a standard Sulforhodamine B assay demonstrated no cellular toxicity associated with three lots of test devices when statistically compared to negative controls.

3.12. Sterilization and Shelf Life
All plastic components of **Puritan UTM-RT** are validated and sterilized following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products-Radiation or by ANSI/AAMI/ISO11135:2007, Sterilization of health care products-ethylene oxide.

Puritan UTM-RT tubes are filled aseptically under control conditions. Representative samples from each lot of **Puritan UTM-RT** are tested according to the USP 34 NF, 29:2011, <71>, Sterility Tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Puritan Medical Products LLC.
C/O Mehdi Karamchi B. Sc. RM (ccm)
Vice President of Scientific Affairs
31 School Street, PO Box 149
Guilford, ME 04443-0149

MAR - 1 2012

Re: K113249
Trade/Device Name: Puritan UTM-RT Collection and Transport System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport culture medium
Regulatory Class: Class I
Product Code: JSM, LIO
Dated: October 28, 2011
Received: December 8, 2011

Dear Mr. Karamchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K113249

Device Name Puritan UTM-RT Collection and Transport System

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Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K113249